



Dkt. 48332-B/JPW/AJM/AG

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Carol M. Troy

Serial No.: 10/665,668

Filed : September 19, 2003

For : COMPOUNDS WHICH PREVENT CELL DEATH AND USES THEREOF

1185 Avenue of the Americas  
New York, New York 10036  
February 4, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicant directs the Examiner's attention to the following disclosures, which are listed on Form PTO-1449 (Exhibit A).

1. Ali, Fadia El-Fehail and Samanen, James Martin, European Patent No. EP 425212, issued April 7, 1999, filed October 22, 1990, Cyclic Anti-Aggregatory Peptides, application published May 2, 1991;
2. Ali, European Patent No. EP 425212;
3. Barinaga, M. (1994) Cell Suicide: By ICE, Not Fire. *Science* 263.: 754-756;
4. Casciola-Rosen, L.A. et al. (1994) Specific Cleavage of

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the 70-kDa Protein Component of the U1 Small Nuclear Ribonucleoprotein Is a Characteristic Biochemical Feature of Apoptotic Cell Death. *J. Bio. Chem.* 269(49):30757-30760;

5. Derossi, D., et al. (1996) Cell Internalization of the third helix of *Antennapedia* homeodomain is receptor-independent. *J. Biol. Chem.* 271, 18188-93;
6. Duggan, M.E. et al. (1995) Non-Peptide Fibrinogen Receptor Antagonists. Design and Synthesis of a Potent, Orally Active Fibrinogen Receptor Antagonist. *J. of Med. Chem.* 38(17):3332-3341;
7. Enari, M., Hug, H. and Nagata, S. (1995) Involvement of an Ice-like protease in Fas-mediated apoptosis. *Nature* 375:78-81;
8. Fernandes-Alnemri, T., Litwack, G. and Alnemri, E.S. (1995) *Mch2*, a New Member of the Apoptotic *Ced-3/Ice* Cysteine Protease Gene Family. *Cancer Res.* 55:2737-2742;
9. Howard et al., European Patent No. EP 533350, Issued May 26, 1999, filed August 14, 1992, DNA Encoding Precursor Interleukin IB Converting Enzyme, application published March 24, 1993;
10. Koivunen, E., Gay, D.A. and Ruoslahti, E. (1993) Selection of Peptides Binding to the Pi Integrin from Phage Display Library. *J. of Biol. Chem.* 27:20205-20210;

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11. Litwack, et al., U.S. Patent Number 5,672,500;
12. Los, M. et al., (1995) Requirement of an ICE/CED-3 protease for Fas/APO-1-mediated apoptosis. *Nature* 375:81-83;
13. Luo, A.-M. et al. (November, 1993) Antigen Mimicry in Autoimmune Disease, Sharing of Amino Acid Residues Critical for Pathogenic T Cell Activation. *AIr??. Soc. For Clin. Invest.* 92:2117-2123;
14. Mashima, T. et al. (1995) Aspartate-Based Inhibitor of Interleukin-1(3)-Converting Enzyme Prevents Antitumor Agent-Induced Apoptosis in Human Myeloid Leukemia U937 Cells. *Biochem. and Biophys. Res. Comm.* 209 (3):907-915;
15. Milligan, C.E. et al. (1995) Peptide Inhibitors of the ICE Protease Family Arrest Programmed Cell Death of Motoneurons In Vivo and In Vitro. *Neuron* 15:385-393;
16. Munday, N.A. et al. (1995) Molecular Cloning and Pro-apoptotic Activity of ICE <sub>rel</sub> II and ICE <sub>rel</sub> III, Members of the ICE/CED-3 Family of Cysteine Proteases. *J. of Biol. Chem.* 270 (26):15870-15876;
17. Prochiantz, A. (1996) Getting hydrophilic compounds into cells: lessons from homeopeptides. *Curr. Opin. Neurobiol.* 6:629-34;
18. Troy, C.M., et al. (1996) Downregulation of Cu/Zn superoxide dismutase leads to cell death via the nitric

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oxide-peroxynitrite pathway. *J. Neurosci.* 16:253-61;

19. Troy. C.M., Compounds Which Prevent Cell Death And Uses Thereof, U.S. Patent No. 6,635,738, issued October 21, 2003 (**Exhibit 1**);
20. Troy. C.M., Compounds Which Prevent Cell Death And Uses Thereof, U.S. Patent Application Publication No. 2002-0044931, published on April 18, 2002 (**Exhibit 2**);
21. Wang, L. et al. (1994) Ich-1, an Ice/ced-3-Related Gene, Encodes Both Positive and Negative Regulators of Programmed Cell Death. *Cell* 78:739-750;
22. Wang, X. et al. (1995) Purification of an Interleukin-13 Converting Enzyme-related Cysteine Protease That Cleaves Sterol Regulatory Element-binding Proteins between the Leucine Zipper and Transmembrane Domains. *J. of Biol. Chem.* 270(30):18044-18055; and
23. Xuan, J.W., et al. (1995) Site-Directed Mutagenesis of the Arginine-Glycine-Aspartic Acid Sequence in Osteopontin Destroys Cell Adhesion and Migration Functions. *J. of Cell. Biochem.* 57:680-690.

The subject application is a divisional of and claims the benefit under 35 U.S.C. §120 of U.S. Serial No. 08/610,220, filed March 4, 1996.

Above-listed references 1, 3, 4, 6-8, 10, 12-16 and 21-23 were submitted to and considered by the United States Patent and

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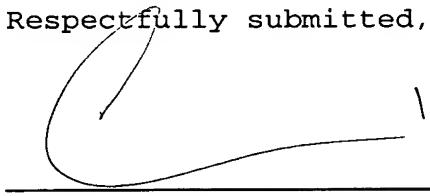
Trademark Office in an Information Disclosure Statement filed on May 14, 1996 in connection with U.S. Serial No. 08/610,220, filed March 4, 1996. Above-listed references 2, 9 and 11 were cited by the United States Patent and Trademark Office in connection with 08/610,220, filed March 4, 1996. Above-listed references 5, 17 and 18 were submitted to and considered by the United States Patent and Trademark Office in a Supplemental Information Disclosure Statement filed on May 18, 2001 in connection with U.S. Serial No. 09/150,623, filed September 4, 1998. Accordingly, under 37 C.F.R. §1.98(d) copies of these references are not required to be provided to the United States Patent and Trademark Office. Copies of above-listed references 19 and 20 are attached hereto as **Exhibit 1** and **2**, respectively.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

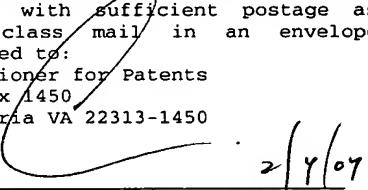
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Pursuant to 37 C.F.R. §1.97(b)(3), no fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

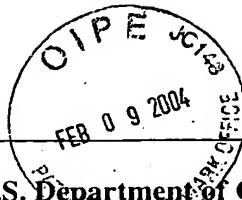
Respectfully submitted,

  
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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:  
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Reg. No. 37,399



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Carol M. TroyFiling Date  
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## U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	5 6 7 2 5 0 0		Litwack, et al.			
	6 6 3 5 7 3 8		Troy, C.M., et al.			
	0 0 4 4 9 3 1		Troy, C.M., et al.			

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Name	Class	Subclass	Translation	
						Yes	No
EP	4 2 5 2 1 2		All				
EP	5 3 3 3 5 0		Howard, et al.				

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Ali, Fadia El-Fehail and Samanen, James Martin, European Patent No. EP 425212, issued April 7, 1999, filed October 22, 1990, Cyclic Anti-Aggregatory Peptides, application published May 2, 1991.
	Barinaga, M. (1994) Cell Suicide: By ICE, Not Fire. <i>Science</i> 263: 754-756;
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	Duggan, M.E. et al. (1995) Non-Peptide Fibrinogen Receptor Antagonists. 7. Design and Synthesis of a Potent, Orally Active Fibrinogen Receptor Antagonist. <i>J. of Med. Chem.</i> 38(17) : 3332-3341;

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		Enari, M., Hug, H. and Nagata, S. (1995) Involvement of an ICE-like protease in Fas-mediated apoptosis. <i>Nature</i> 375:78-81;
		Fernandes-Alnemri, T., Litwack, G. and Alnemri, E. S. (1995) <i>Mch2</i> , a New Member of the Apoptotic <i>Ced-3/Ice</i> Cysteine Protease Gene Family. <i>Cancer Res.</i> 55:2737-2742;
		Koivunen, E., Gay, D.A. and Ruoslahti, E. (1993) Selection of Peptides Binding to the $\alpha^{\text{b}}$ Integrin from Phage Display Library. <i>J. of Biol. Chem.</i> 27:20205-20210;
		Los, M. et al. (1995) Requirement of an ICE/CED-3 protease for Fas/APO-1-mediated apoptosis. <i>Nature</i> 375:81-83;

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	Luo, A.-M. et al. (November, 1993) Antigen Mimicry in Autoimmune Disease, Sharing of Amino Acid Residues Critical for Pathogenic T Cell Activation. <i>AIr? Soc. for Clin. Invest.</i> 92:2117-2123;
	Mashima, T. et al. (1995) Aspartate-Based Inhibitor of Interleukin-1(3-Converting Enzyme Prevents Antitumor Agent-Induced Apoptosis in Human Myeloid Leukemia U937 Cells. <i>Biochem. and Biophys. Res. Comm.</i> 209 (3):907-915;
	Milligan, C.E. et al. (1995) Peptide Inhibitors of the ICE Protease Family Arrest Programmed Cell Death of Motoneurons In Vivo and In Vitro. <i>Neuron</i> 15:385-393;
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	Troy, C.-M., et al. (1996) Downregulation of Cu/Zn superoxide dismutase leads to cell death via the nitric oxide-peroxynitrite pathway. <i>J. Neurosci.</i> 16:253-61
	Wang, L. et al. (1994) Ich-1, an <i>Ice</i> /ced-3-Related Gene, Encodes Both Positive and Negative Regulators of Programmed Cell Death. <i>Cell</i> 78:739-750;
	Wang, X. et al. (1995) Purification of an Interleukin-1 $\beta$ Converting Enzyme-related Cysteine Protease That Cleaves Sterol Regulatory Element-binding Proteins between the Leucine Zipper and Transmembrane Domains. <i>J. of Biol. Chem.</i> 270(30) :18044-18055 ;
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